FDAMA STAKEHOLDER MEETING

APRIL 28, 1999

Talking with Stakeholders About FDA Modernization

✓ Site: Chicago, IL

**Your question/comments will become part of Docket Number: 99N-0386

Fax to: 1-888-361-4011 (on April 28 only)

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Title (required) ☐Dr. ☐Mr. ☐Mrs. ☒Ms.

First Name (required) Debra

Last Name (required) Bullock, BA, MTS

Organization Valence Research, LLC

Stakeholder Group ✓ stakeholder group you represent

☐ Consumer ☐ Consumer Group ☐ Health Professional ☐ Industry ☐ Association ☑ Other

Center ✓ the center/product area your comments address

☐ Center for Biologics
☐ Center for Devices and Radiological Health
☐ Center for Veterinary Medicine
☐ FDA General
☑ Center for Drug Evaluation and Research
☐ Center for Food Safety and Applied Nutrition
☐ Office of Regulatory Affairs

Questions to Stakeholders

Please check the box next to the stakeholder question/s from the March 22, 1999, Federal Register notice which your question/comment addresses.

- ☐ 1. What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?
- ☐ 2. What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?
- ☑ 3. What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?
- ☐ 4. What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?
- ☐ 5. What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?
- ☐ 6. Additional Comments on FDA Modernization Efforts.

YOUR COMMENT/QUESTION

– What initiatives has the FDA taken to encourage the participation of minority groups in clinical drug trials? Since Tuskegee incident, for example, the recruitment of African-Americans into drug trials has become all but impossible.

– NIH requires pediatric involvement in NIH-sponsored research. Does FDA anticipate moving industry-sponsored research in a similar direction? Other than pediatric exclusivity, what other initiatives is FDA taking? C26

99N-0386